

Remarks

Claims 1-3, 5, 6, 8, 9, 11-16, 18-24, 27-29, 31-58, 62-74, and 77-79 were pending in the subject application. By this Amendment, claims 8 and 15 have been amended, and claims 6, 9, 12, 14, 16, 18, 27-29, 33, 35-58, 62-74, 77, and 78 have been cancelled. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of the applicants' agreement with or acquiescence in the Examiner's position. Accordingly, claims 1-3, 5, 8, 11, 13, 15, 19-24, 31, 32, 34, and 79 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Submitted herewith is a Request for Continued Examination (RCE) under 37 C.F.R. §1.114 for the subject application.

The applicants acknowledge that claims 40-58 and 62-74 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, claims 40-58 and 62-74 have been cancelled.

The applicants and the applicants' representative wish to thank Examiner Naff for the courtesy of the telephonic interview conducted with the undersigned on July 17, 2007, regarding the rejections under 35 U.S.C. §102(b) and §103(a). The remarks and amendments set forth herein are consistent with the substance of the interview and are believed to address the outstanding issues as discussed during the interview.

Claims 1-3, 5, 8, 11-13, 15, 24, 27-29, 31, and 77-79 have been rejected under 35 U.S.C. §102(b) as being anticipated by Olszta (R9 on 1449 of 5/12/04) or Olszta (R11 on 1449 of 5/12/04) or Olszta (R27 on 1449 of 3/15/04). The applicants respectfully traverse.

As an initial matter, the applicants respectfully submit that if a rejection is to be set forth based on the cited references under 35 U.S.C. §102 (and the applicants submit that it should not), the appropriate statutory authority is 35 U.S.C. §102(a), not §102(b). Written support for the currently pending claims can be found throughout the priority application 60/373,801, filed April 18, 2002, which was incorporated by reference into the parent application, serial number 10/418,843, and the

subject application. The effective dates of the Olszta R9, Olszta R11, and Olszta R27 publications are November 2001, March 2002, and June 2001, respectively, each of which are less than one year prior to the earliest effective priority date of the subject application. Thus, the rejection under 35 U.S.C. §102(b) is not proper.

Support for claims 1-3 and 11 can be found, for example, at pages 1-3, paragraphs 0002 and 0005; page 5, paragraphs 0008-0010; page 8, paragraph 0020; page 9, paragraph 0025; page 10, paragraph 0028; page 11, paragraph 0030; page 20, paragraph 0064 and 0065, of the provisional application 60/373,801. Support for claim 5 can be found, for example, at page 20, paragraph 0064, of the provisional application 60/373,801. Support for claim 8 can be found, for example, at page 12, paragraph 0035; and page 14, paragraph 0044, of the provisional application 60/373,801. Support for claim 13 can be found, for example, at page 5, paragraph 0009; page 10, paragraph 0028, of the provisional application 60/373,801. Support for claim 15 can be found, for example, at page 5, paragraph 0008, of the provisional application 60/373,801. Support for claims 19-23 and 32 can be found, for example, at pages 13-15, paragraphs 0041-0047, of the provisional application 60/373,801. Support for claims 24 and 34 can be found, for example, at page 13, paragraphs 0039-0040, of the provisional application 60/373,801. Support for claim 31 can be found, for example, at page 12, paragraph 0035; page 16, paragraphs 0051 and 0053, of the provisional application 60/373,801. Support for claim 79 can be found, for example, at page 5, paragraph 0010; page 9, paragraph 0025; and page 10, paragraph 0028, of the provisional application 60/373,801. Thus, written support for the currently pending claims can be found within the priority application 60/373,801, which the subject application claims the benefit of priority.

The applicants' respectfully submit that the Olszta R27 reference is material presented at a Gordon Research Conference, which does not qualify as a publication under 35 U.S.C. §§ 102 and 103. Submitted herewith as Exhibit A is information printed from the Gordon Research Conferences Home Page. As stated in the "format" section at page 2 of Exhibit A,

To encourage open communication, each member of a Conference agrees that any information presented at a Gordon Research Conference, whether in a formal talk, poster session, or discussion, is a private communication from the individual making the contribution and is presented with the restriction that such information is not for public use. The recording of lectures by any means, the photography of slide or poster material,

and printed reference to Gordon Research Conferences papers and discussion is prohibited. Scientific publications are not to be prepared as emanating from the Conferences. Authors are requested to omit references to the Conferences in any publication. Guests are not permitted to attend the Conference lectures and discussion sessions. Each member of a Conference acknowledges and agrees to these restrictions when registration is accepted and as a condition of being permitted to attend a Conference...

Thus, the Olszta R27 reference was not disclosed to conference attendees without restriction. In view of the policy established for the Gordon Research Conference, and the agreement by conference attendees, there was a reasonable expectation of confidentiality.

Furthermore, the applicants respectfully submit that the Olszta R9, Olszta R11, and Olszta R27 references are disqualified as prior art under 35 U.S.C. §§ 102 and 103 because the subject matter disclosed in the references and relied on in the rejections was not the work of “another”, as required for a rejection under § 102 or § 103, but rather originated with the applicants of the subject application.

Where the applicant is one of the co-authors of a publication cited against his or her application, ... the applicant may overcome the rejection by filing a specific affidavit or declaration under 37 C.F.R. §1.132 establishing that the article is describing applicant's own work. An affidavit or declaration by applicant alone indicating that applicant is the sole inventor and that the others were merely working under his or her direction is sufficient to remove the publication as a reference under 35 U.S.C. §102(a). *In re Katz*, 687 F.2d 450; 215 USPQ 14 (CCPA 1982); MPEP 715.01(c); 706.02(b).

On December 20, 2006, the applicants submitted a Declaration by Dr. Laurie B. Gower under 37 C.F.R. §1.132, a named inventor on the subject application. As is made clear in the Declaration, the subject matter disclosed in the cited references, and relied on by the Examiner, was the invention of the inventors on the subject application. An uncontradicted, unequivocal statement from the applicants regarding the subject matter disclosed in an article, patent, or published application will be accepted as establishing inventorship. *In re DeBaun*, 687 F.2d 459, 463; 214 USPQ 933, 936 (CCPA 1982); *Ex parte Kroger*, 218 USPQ 370 (Bd. App. 1982); MPEP 716.10. It is the person or persons who are the first to conceive the invention as claimed in a patent application who are the inventors. Conception can be defined as “the formation, in the mind of the inventor, of a definite and permanent

idea of the complete and operative invention, as it is thereafter to be applied in practice”. *Hybritech Incorporated v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 87 (Fed Cir. 1986) quoting 1 Robinson on Patents 532 (1890); *Coleman v. Dines*, 224 USPQ 857, 862 (Fed. Cir. 1985).

It was indicated by the Examiner during the telephonic interview of July 17, 2007, and reiterated in the Interview Summary mailed July 20, 2007, that “invention requires both conception and reduction to practice”. MPEP 2137.01 speaks directly to this issue:

The definition for inventorship can be simply stated: “The threshold question in determining inventorship is **who conceived the invention**. Unless a person contributes to the conception of the invention, he is not an inventor. ... Insofar as **defining an inventor** is concerned, **reduction to practice, per se, is irrelevant** [except for simultaneous conception and reduction to practice, *Fiers v. Revel*, 984 F.2d 1164, 1168, 25 USPQ2d 1601, 1604-05 (Fed. Cir. 1993)]. One must contribute to the conception to be an inventor.” *In re Hardee*, 223 USPQ 1122, 1123 (Comm’r Pat. 1984). (emphasis added)

As articulated in MPEP 2137.01II, difficulties arise in separating members of a team effort, where each member of the team has contributed something, into those members that actually contributed to the conception of the invention, from those that did not. However, the inventor is not required to reduce the invention to practice to be an inventor. It is not necessarily essential for the inventor to be personally involved in carrying out process steps. Thus, while a patentable invention requires a constructive or actual reduction to practice, inventorship does not.

Furthermore, submitted herewith as Exhibit B are relevant portions of a grant proposal to the National Science Foundation (redacted), which was prepared prior to the subject application’s priority date. Dr. Elliot P. Douglas is listed as the principal investigator and Dr. Laurie B. Gower is listed as the co-principal investigator. As explained in Dr. Gower’s Declaration, Dr. Douglas, Dr. Olszta, and Dr. Gower contributed to the conception of mineralizing a collagen matrix using an inorganic mineral phase, resulting in a biomimetic organic/inorganic composite. Joint inventors must have “some quantum of collaboration or connection” and contribute to at least one element of the claims. However, inventors may file jointly even if they did not work together at the same location at the same time, or each did not make the same kind or amount of contribution, or each did not make a contribution to the subject matter of every claim of the patent. *Monsanto Co. v. Kamp*, 154 USPQ 259, 262 (D.D.C. 1967). Exhibit B provides further evidence of such collaboration. The

experiments described in the Olszta R9, R11, and R27 presentations, which were carried out by Dr. Olszta and Dr. Gower, confirmed that the process to make the organic/inorganic composite originally conceived through collaboration by Dr. Douglas, Dr. Olszta, and Dr. Gower worked for its intended purpose. As explained by Dr. Gower, Dr. Douglas did not participate directly in the Olszta R9, R11, and R27 presentations and was not directly involved in carrying out the experiments described in the presentations; however, it is only for these reasons that Dr. Douglas was not included as a co-author of these presentations. As indicated in the applicants' previous response, the requirements for authorship and inventorship are not the same. Authorship of a publication does not give rise to any presumption with respect to inventorship.

Therefore, the Olszta R9, Olszta R11, and Olszta R27 presentations cannot be used as prior art references against the applicants' claimed invention. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b) is respectfully requested.

Claims 6, 16, and 18 have been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Silver *et al.* (U.S. Patent No. 5,532,217). Claims 9 and 14 have been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Rhee *et al.* (U.S. Patent No. 5,800,541). Claims 19-21 and 23 have been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Liu (U.S. Patent No. 6,300,315 B1). Claims 22 has been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Liu (U.S. Patent No. 6,300,315 B1) and further in view of Rhee *et al.* (U.S. Patent No. 5,800,541). Claims 32, 33, 35, and 36 have been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Connelly *et al.* (U.S. Patent No. 6,995,013 B2). Claims 34 and 37-39 have been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Song *et al.* (U.S. Patent No. 5,418,222). The applicants respectfully traverse.

Each of the rejections under 35 U.S.C. §103(a) are based on the Olszta R9, R11, and R27 presentations as primary references. Accordingly, the applicants' remarks in response to the rejections under 35 U.S.C. §102(b) based on these three references individually, are incorporated herein by reference in their entirety. In particular, written support for the currently pending claims can be found throughout the priority application 60/373,801, filed April 18, 2002, which was incorporated by reference into the parent application, serial number 10/418,843, and the subject

application. The effective dates of the Olszta R9, Olszta R11, and Olszta R27 publications are November 2001, March 2002, and June 2001, respectively, each of which are less than one year prior to the earliest effective priority date of the subject application. Thus, the rejection under 35 U.S.C. §102(b) is not proper. In addition, the applicants respectfully submit that the Olszta R27 reference is material presented at a Gordon Research Conference, which does not qualify as a publication under 35 U.S.C. §§ 102 and 103. Furthermore, the applicants respectfully submit that the Olszta R9, Olszta R11, and Olszta R27 references are disqualified as prior art under 35 U.S.C. §§ 102 and 103 because the subject matter disclosed in the references and relied on in the rejections was not the work of “another”, as required for a rejection under § 102 or § 103, but rather originated with the applicants of the subject application.

The other cited references do not teach or suggest the applicants’ claimed invention. The Silver *et al.*, Rhee *et al.*, Liu, and Connelly *et al.* references do not teach or suggest the biomimetic organic/inorganic composite recited in the currently pending claims. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) is respectfully requested.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Request for Continued Examination
Petition and Fee for Extension of Time
Exhibits A and B